

Notice of Allowability

Application No.

10/091,166

Examiner

Chih-Min Kam

Applicant(s)

ADLER ET AL.

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 4/5/07.
2. ☒ The allowed claim(s) is/are 1-5, 21-24 and 51.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

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DETAILED ACTION

Status of the Claims

1. Claims 1-5, 21-24, 45, 46 and 50 are pending.

Applicants' amendments filed April 5, 2007 is acknowledged. Applicants' response has been fully considered. Claim 25 has been cancelled. Therefore, claims 1-5, 21-24, 45, 46 and 50 are examined.

Withdrawn Claim Rejections - 35 USC § 112

2. The previous rejection of claim 25 under 35 U.S.C. 112, first paragraph, is withdrawn in view of applicants' cancellation the claim, and applicants response at page 5 in the amendment filed April 5, 2007.

Examiner's Amendment

An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Brian Walsh on June 18, 2007.

Examiner's Amendment to the Specification:

Please replace the paragraph originally cited at page 1, line 8 of the specification and later amended at pages 1-2 in the preliminary amendment filed March 5, 2002 with the following paragraph:

The present application is a divisional application of U.S. Patent Application Serial No. 09/636,399, filed August 10, 2000, now U. S. Patent 6,576,755, which is a continuation-in-part of U.S. Patent Application No. 09/344,097, filed on June 25, 1999, now abandoned, which is a continuation-in-part of U.S. Patent Application No. 09/150,786, filed on September 10, 1998, now abandoned, which is related to Provisional Applications 60/058,335, filed on September 10,

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1997 and 60/064,294, filed on November 5, 1997, all of which are herein incorporated by reference. Under 35 U.S.C. § 119(e)(1), this application claims benefit of said Provisional Applications.

Examiner's Amendment to the Claims:

Claims 45, 46 and 50 have been cancelled.

Claims 1, 3-5 and 21 have been amended and a new claim 51 has been added as follows:

Claim 1 (Currently amended): An isolated protein comprising a polypeptide that is at least 95% identical to amino acid residues ~~23~~ 21 to ~~67~~ 65 of ~~SEQ ID NO: 10~~ SEQ ID NO:2; wherein the polypeptide has antimicrobial activity.

Claim 3 (Currently amended): The isolated protein of claim 1 wherein the polypeptide comprises amino acid residues ~~23~~ 21 to ~~67~~ 65 of ~~SEQ ID NO: 10~~ SEQ ID NO:2.

Claim 4 (Currently amended): An isolated polypeptide comprising an amino acid sequence selected from the group consisting of:

- a) amino acid residue 30 to amino acid residue 63 of SEQ ID NO:2;
- b) amino acid residue 31 to amino acid residue 63 of SEQ ID NO:2;
- c) amino acid residue 30 to amino acid residue 64 of SEQ ID NO:2;
- d) amino acid residue 31 to amino acid residue 64 of SEQ ID NO:2; and
- e) amino acid residue ~~23~~ 21 to amino acid residue ~~67~~ 65 of ~~SEQ ID NO: 10~~ SEQ ID NO:2, wherein the polypeptide has antimicrobial activity.

Claim 5 (Currently amended): A pharmaceutical composition comprising a polypeptide comprising an amino acid sequence selected from the group consisting of:

- a) ~~a protein according to claim 1~~ amino acid residue 1 to amino acid residue 65 of SEQ ID NO:2;
- b) amino acid residue 30 to amino acid residue 63 of SEQ ID NO:2;

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- c) amino acid residue 31 to amino acid residue 63 of SEQ ID NO:2;
- d) amino acid residue 30 to amino acid residue 64 of SEQ ID NO:2;
- e) amino acid residue 31 to amino acid residue 64 of SEQ ID NO:2; and
- f) amino acid residue ~~23~~ 21 to amino acid residue ~~67~~ 65 of ~~SEQ ID NO: 10~~ SEQ ID NO:2;

in combination with a pharmaceutically acceptable vehicle, wherein the polypeptide has antimicrobial activity.

Claim 21 (Currently amended): A method of treating a microbial-related disease in a mammal comprising administering to the mammal a therapeutically effective amount of a polypeptide comprising an amino acid sequence selected from the group consisting of:

- a) amino acid residue 1 to amino acid residue 65 of SEQ ID NO:2;
- ~~b) amino acid residue 23 to amino acid residue 67 of SEQ ID NO:10;~~
- ~~c) amino acid residue 1 to amino acid residue 67 of SEQ ID NO:10;~~
- ~~d) amino acid residue 30 to amino acid residue 63 of SEQ ID NO:2;~~
- ~~e) amino acid residue 31 to amino acid residue 63 of SEQ ID NO:2;~~
- ~~f) amino acid residue 30 to amino acid residue 64 of SEQ ID NO:2; and~~
- ~~g) amino acid residue 31 to amino acid residue 64 of SEQ ID NO:2;~~
- ~~h) amino acid residue 20 to amino acid residue 67 of SEQ ID NO:10; and~~
- ~~i) amino acid residue 22 to amino acid residue 67 of SEQ ID NO:10;~~

wherein said polypeptide ameliorates said disease.

Claim 51 (New): A pharmaceutical composition comprising a polypeptide that is at least 95% identical to amino acid residues 21 to 65 of SEQ ID NO:2 and a pharmaceutically acceptable carrier, wherein the polypeptide has antimicrobial activity.

The following is an Examiner's Statement of Reasons for Allowance: The following reference appears to be related to the claimed invention. McCray *et al.* (U. S. Patent 6,809,181, filed on June 1, 2001; priority date June 1, 2000) claims an isolated peptide comprising the amino acid sequence of SEQ ID NO:2 (residues 1-67, corresponding to SEQ ID NO:10 of the

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instant application), SEQ ID NO:3 (residues 27-67 of SEQ ID NO:2) or SEQ ID NO:4 (residues 23-67 of SEQ ID NO:2), wherein the antimicrobial peptide is contained in a pharmaceutical composition for oral administration; and a method of inhibiting growth of a microbe in a host comprising orally administering to the host the antimicrobial peptide. However, the patent does not teach or suggest an antimicrobial peptide of residues 1-65, 21-65, 30-63, 30-64, 31-63 or 31-64 of SEQ ID NO:2 (residues 1-65), or a method of treating a microbial-related disease in a mammal using the antimicrobial peptide. Furthermore, the instant application has at least a priority date of November 5, 1997 regarding the amino acid sequence of SEQ ID NO:2 and SEQ ID NO:10. Therefore, the claims are allowable over the art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Chih-Min Kam, Ph. D.

Primary Patent Examiner



CHIH-MIN KAM
PRIMARY EXAMINER

CMK

June 18, 2007